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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,511	10/06/2000	Raymond Andersen	P108281-0000	6795

7590 06/03/2003

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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,511

Applicant(s)

ANDERSEN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-74 is/are pending in the application.
- 4a) Of the above claim(s) 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Pursuant to the directives of paper No. 18 (filed 5/12/03), claims 22 68 70 73 74 have been amended. Claims 22-74 remain pending. Claim 74 remains withdrawn from consideration at this time.

Applicants' arguments filed 5/12/03 have been considered and found persuasive in part. The rejection of claims 22-73 under 35 U.S.C. 112, first paragraph is withdrawn. The rejection of claims 22-26, 60, 62, 68-70 as anticipated by Webber ('799) is also withdrawn.

*

Claims 22-73 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 22, the following is recited:

"R is a saturated or unstaurated moiety.... substituted with: =O, =S, OH, ...-I, -Br, -C1, -F, -CN"

Between "-Br" and "-F", the term "-C1" is recited, i.e., the letter "C" followed by the number "1". However, it appears that the letter "I" is intended rather than the number "1".

- In claim 73, the indefinite article ("an") should precede "acceptable pharmaceutical excipient".

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 23, 25, 47, 60, 68, 70 are rejected under 35 U.S.C. §102(b) as being anticipated by Reetz (*Angew. Chem., Int. Ed. Engl.*, **31**(12), 1626-9, 1992).

Reetz discloses compounds 11 and 13 (page 1627, col 2), which are diastereomers of one another. (The stereochemistry is "L,L,L" and "D,L,L", respectively). Both of these correspond to the substituent variables of claim 22 as follows.

R1 = hydrogen
R2 = tBoc
R3 = hydrogen
R4 = hydrogen
R5 = phenyl
R6 = hydrogen
R7 = methyl
R8 = hydrogen
Y = propylene substituted with isobutyl
Z = -O-CH₂-CH₃

As indicated above, substituent variable R₂ can be tert-butyloxycarbonyl. This is because R₂ can be R, and R, in turn can be "branched skeleton" that **contains** one oxygen atom, and which may be **substituted** with oxo. Thus, beginning with the following "branched skeleton": (Me)₃C-CH₂-CH₂- and replacing the terminal methylene group with oxo, and

the internal methylene group with an oxygen atom yields a *tert*-butyloxycarbonyl group.

Claim 23 is rejected, since this claim does not require that any of the substituent variables be limited in any way. Claim 68 is rejected, as it encompasses both the "S, R" and the "S, S" stereochemistry; claim 70 encompasses both the "R, S", and the "S, S" stereochemistry.

Thus, the claims are anticipated.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 6/2/03

Chris Low

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